



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,093	10/15/2001	Oliver Muller	QGN-020.0P US	7926

7590 06/03/2004
Leon R. Yankwich
YANKWICH & ASSOCIATES
201 Broadway
Cambridge, MA 02139

EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
----------	--------------

1636

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/889,093	Applicant(s) MULLER ET AL.	
	Examiner Konstantina Katcheves	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004 and 06 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/10/2001; 9/4/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 15-34 are pending in the present application.

Response to Arguments

The rejections set forth in the Office action mailed 6 October 2003 are moot in view of the new grounds of rejection set forth below. Applicant's arguments filed 5 March 2004 and 6 January 2004 have been fully considered. However, given the new art presented those arguments have been rendered moot and will not be addressed unless directly pertinent to the new grounds of rejection below.

New Grounds of Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1636

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 17, 19-21, 26, 27 and 32-34 of U.S. Patent No. 6,084,091 in view of Wan et al. (Analytical Biochemistry Vol.223 pages 7-12 1994).

The claims of the present application are drawn to a method for purifying nucleic acids in a biological sample comprising contacting the sample with a buffer having a pH from about 2 to about 8 and a salt concentration of at least about 100 mM and comprising a phenol neutralizing substance, polyvinylpyrrolidone (PVP), contacting the extraction buffer and sample to an adsorption matrix, potato flour, and isolating the nucleic acid.

The '091 patent teaches a method of purifying nucleic acids in a biological sample, including stool, comprising providing an extraction buffer and contacting the sample with an adsorption matrix comprising a carbohydrate or potato flour. The '091 patent fails to teach the buffer comprising a phenol-neutralizing substance and a salt concentration of at least about 100 mM. The '091 patent does teach that the buffer may have a pH of 8.5-9.5, *i.e.* about 8, and does teach that the buffer may have a salt concentration of about 10 mM. The '091 patent also teaches that the buffer be suitable for taking up a specimen containing nucleic acids and may include other reagents or buffer solutions. See column 5, lines 7-15 and column 2 line 45.

Art Unit: 1636

Wan et al. teach methods for isolating nucleic acids comprising using buffer adjuvants that significantly impact yield and quality of nucleic acids. Of the buffer adjuvants tested polyvinylpyrrolidone produced the best results. The extraction buffer was supplemented with PVP and additionally 160 mM potassium chloride, KCl, was added to the buffer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate nucleic acids by contacting the sample with a buffer having a pH from about 2 to about 8, as taught by the '091 patent, and a salt concentration of at least about 100 mM and comprising a phenol neutralizing substance, polyvinylpyrrolidone (PVP), as taught by Wan et al. contacting the extraction buffer and sample to a potato flour adsorption matrix as taught by the '091 patent and isolating the nucleic acid. One of skill in the art would have been motivated to optimize the salt concentration of the '091 patent because optimization of amounts is well-within the purview of the ordinary skilled artisan. According to MPEP 2144.05: "differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical." Moreover, Wan et al. actually teach a buffer comprising PVP and 160 mM KCl. One of ordinary skill in the art would have been motivated to use PVP in a buffer which because of the increased yield and quality of nucleic acids it provides. Because the isolation of nucleic acids is so routine in the art, one of skill in the art would reasonably expect success of the present method. Therefore, the invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made.

Art Unit: 1636

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (WO 97/07239, translation provided) in view of Wan et al.

The invention of the instant claims of the present application are drawn to a method for purifying nucleic acids in a biological sample comprising contacting the sample with a buffer having a pH from about 2 to about 8 and a salt concentration of at least about 100 mM and comprising a phenol neutralizing substance, polyvinylpyrrolidone (PVP), contacting the extraction buffer and sample to an adsorption matrix, potato flour, and isolating the nucleic acid. Other embodiment of the present invention include various temperatures for incubation and the addition of other physical conditions such as centrifugation, reduced pressure or gravity or chemical, thermal or enzymatic treatment during the incubation of the sample with the extraction buffer.

WO 97/07239 (Muller et al.) is the foreign equivalent of the '091 patent for which a translation has been provided. Muller et al. teach a method of purifying nucleic acids in a biological sample, including stool, comprising providing an extraction buffer and contacting the sample with an adsorption matrix comprising a carbohydrate or potato flour. Muller et al. fail to teach the buffer comprising a phenol-neutralizing substance and a salt concentration of at least about 100 mM. Muller et al. do teach that the buffer may have a pH of 9, *i.e.* about 8, and does

Art Unit: 1636

teach that the buffer may have a salt concentration of about 10 mM. See page 12. Muller et al. patent also teach that the buffer be suitable for taking up a specimen containing nucleic acids and may include other reagents or buffer solutions or enzymes. See page 12, para 1 and page 10, para. 2-4. Muller et al. also teach that the sample and buffer may be incubated at room temperature and physical conditions may be applied such as gravity. See page 7, bridging para.

Wan et al. teach methods for isolating nucleic acids comprising using buffer adjuvants that significantly impact yield and quality of nucleic acids. Of the buffer adjuvants tested polyvinylpyrrolidone produced the best results. The extraction buffer was supplemented with PVP and contacted with the sample additionally 160 mM potassium chloride, KCl, was added to the buffer.

As discussed above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate nucleic acids by contacting the sample with a buffer having a pH from about 2 to about 8, as taught by Muller et al., and a salt concentration of at least about 100 mM and comprising a phenol neutralizing substance, polyvinylpyrrolidone (PVP), as taught by Wan et al. contacting the extraction buffer and sample to a potato flour adsorption matrix, as taught by the Muller et al, and isolating the nucleic acid. One of skill in the art would have been motivated to optimize the salt concentration or other conditions such as temperature and gravity or add enzymes to the solutions of Muller et al. patent because optimization of amounts is well-within the purview of the ordinary skilled artisan. According to MPEP 2144.05: “differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.” Moreover, Wan et al. actually teach a buffer comprising PVP and 160

Art Unit: 1636

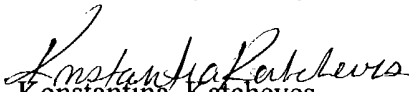
mM KCl. One of ordinary skill in the art would have been motivated to use PVP in a buffer which because of the increased yield and quality of nucleic acids it provides. Because the isolation of nucleic acids is so routine in the art, one of skill in the art would reasonable expect success of the present method. Therefore, the invention, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Konstantina Katcheves
Examiner
Art Unit 1636